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09/382,433 08/25/1999		08/25/1999	JOHN G. STARK	2947.03US02	5227
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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	09/382,433	STARK ET AL.					
Office Action Summary	Examiner	Art Unit					
	Denise M Pothier	3764					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with t	he correspondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	36(a). In no event, however, may a reply within the statutory minimum of thirty (30 iil apply and will expire SIX (6) MONTHS cause the application to become ABAND	be timely filed) days will be considered timely. from the mailing date of this communication. ONED (35 U.S.C. § 133).					
1) Responsive to communication(s) filed on 23 J	<u>anuary 2003</u> .						
2a) ☐ This action is FINAL . 2b) ☑ Thi	is action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4)⊠ Claim(s) <u>24-31 and 50-59</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdraw	vn from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>24-31 and 50-59</u> is/are rejected.							
7)⊠ Claim(s) <u>54-55</u> is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accep	ted or b) objected to by the I	Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents	s have been received.						
2. Certified copies of the priority documents have been received in Application No							
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received.							
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 		mary (PTO-413) Paper No(s) mal Patent Application (PTO-152) .					

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DETAILED ACTION

Summary

1. The Examiner sincerely apologizes for the confusion of the last Office Action. As Applicants indicate, Invention II drawn to an ambulatory orthosis system was elected in Paper No. 15. Therefore, claim 50 should have been examined. The grounds for the restriction remains proper, but since the examination of claims 24-31 has been performed, an examination of all pending claims is included in this Office Action.

Claim Objections

2. Claims 54-55 are objected to because of the following informalities: since it appears that the knee and elbow are integral components of the claim. To overcome this objection, the Examiner suggests recited – during use – after "knee" in claim 54 and after "elbow" in claim 55. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 4. Claims 50-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 50 recites the limitation, "the ambulatory orthosis system support" and "the ambulatory orthosis support" in line 10. There is insufficient antecedent basis for these

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limitations in the claim. Applicants have previously recited "ambulatory orthosis system" in line 1.

6. The remaining claims are necessarily rejected because they depend from a rejected claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 24, 26-27, 29-31, 50-52, and 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman (4,986,981). Zimmerman discloses in Figures 1-2 and 6 and in column 2, lines 28-54 a method of performing coordination exercises for neuromotor training, the method comprising flexing a first joint (wrist col. 5, I. 40-46 and fingers/thumb –col. 4, I. 22-24) such that a cursor (26) on a display (28) moves to reach a target position (pick up object, such as that in Fig. 2 and col. 8, I. 12-26) on the display (see Figs. 1-2) at a selected, predetermined time, the motion of the cursor being correlated with the motion or strain of the joint by way of a sensor (flex sensor) in an ambulatory orthosis (glove 12) placed at the joint (seen best in Fig. 2;col. 4, I. 19-52 and

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col. 5, I. 38-46), the ambulatory orthosis comprising a support portion (glove 12) that fits around the joint such that the ambulatory orthosis is carried by the patient during the flexing step.

As for claim 26, Zimmerman discloses in Figure 2, in column 2, lines 28-36, in column 3, lines 56-64 and in column 4, lines 54-64 that the sensor is operably connected to a portable controller (chip 48) comprising a digital microprocessor. In addition, the computer/controller (16) is portable and the sensor is operably connected to it (col. 3, l. 16-19).

As for claims 27 and 31, Zimmerman discloses in column 4, lines 19-52 and in column 5, lines 38-46 that the cursor motion (26) is correlated with the strain of the joint by way of a flex sensor (40) that provides a signal of the degree of bending of the fingers.

As for claim 29, Zimmerman discloses in column 3, lines 31-46 and column 4, lines 19-52 the step of flexing a second joint (flexing another finger or thumb) to simultaneously vary the display along with motion of the first joint, wherein variations in the display due to the motion of the second joint is determined by the output of a position or strain sensor (another flex sensor 40) at the second joint.

As for claim 30, see the above discussion of claim 26 and column 3, lines 31-36 and column 4, lines 19-64 discussing how the sensors are operably connected to a portable controller comprising a digital microprocessor, the microprocessor providing a target (object; col. 8, I. 10-36) for the flexing of the joints on the display.

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As for claim 50, Zimmerman discloses in Figures 1, 2 and 6 an ambulatory orthosis system comprising a display (28), a support portion (includes 12) that is capable of fitting around a joint (fingers/thumb - col. 4, I. 22-24 and wrist - col. 5, I. 40-46) and is carried by the patient during use and a sensor (flex sensors 40 – col. 4, I. 19 or col. 5, I. 44-46) on the support portion (see Fig. 2), and a controller (includes 14,16,48) operably connected (col. 2, I. 28-36, col. 3, I. 16-19 and 56-64, col. 4, I. 54-64) to the sensor, wherein the controller controls the display based on the signals from the sensor and wherein the patient, flexing the joint, causes a cursor movement on the display, in which the motion of the cursor is correlated with the motion or strain of the joint as detected by the sensor in the ambulatory orthosis system support (col. 4, I. 19-52 and col. 5, I. 38-46) when the ambulatory orthosis support is associated with the joint of the patient.

As for claim 51, see the above discussion of claim 26.

As for claim 52, Zimmerman discloses in Figures 1-2 that the display is integral with the portable controller (through cables, including 13).

As for claim 56, Figures 2 and 6 and column 8, lines 19-29 of Zimmerman provides examples of the display having targets (disk in Fig. 2 and objects) to be reached by the patient through the joint movement.

As for claim 57, see the above discussion of claims 27 and 31.

9. Claims 24, 50, 53, 56 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Walton (5,989,157). Walton discloses in Figures 1, 13, 18, and 20-22 a method of performing coordination exercises for neuromotor training, the method

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comprising flexing a first joint (vertebrae joint about the waist or wrist) such that a cursor (e.g. 235) on a display (20) moves to reach a target position on the display (track) at a selected, predetermined time, the motion of the cursor being correlated with the motion or strain of the joint by way of a sensor (accelerometer) in an ambulatory orthosis (2-4) placed at the joint (e.g. Figs. 4-6;col. 5, I. 54-56, col. 6, I. 14-31, col. 8, I. 46-52, col. 11, I. 3-6 and 63-67 and col. 12, I. 1-12), the ambulatory orthosis comprising a support portion (2-4) that fits around the joint such that the ambulatory orthosis is carried by the patient during the flexing step.

As for claim 50, Walton discloses in Figures 1, 4-6, 18, and 20-21 an ambulatory orthosis system comprising a display (20 in Fig. 1), a support portion (includes 2-4; col. 4, I. 52-58) that is capable of fitting around a joint (col. 4, I. 53 and col. 6, I. 21-24 states can be mounted on waist (vertebrae joints) or wrist and Figs. 4-6 shows unit on waist and wrist) and is carried by the patient during use and a sensor (includes accelerometers and strains gages; col. 4, I. 66-col. 5, I. 2) on the support portion (see Figs. 1-2 showing these sensors are part of unit 2), and a controller (includes 17 shown in Fig. 3 and described in col. 5, I. 19-62) operably connected (col. 5, I. 9-16) to the sensor, wherein the controller controls the display based on the signals from the sensor (such as that described in col. 5, I. 37-55) and wherein the patient, flexing the joint, causes a cursor movement on the display, in which the motion of the cursor is correlated with the motion or strain of the joint as detected by the sensor in the ambulatory orthosis system support (col. 5, I. 54-56, col. 6, I. 14-31, col. 8, I. 46-52, col.

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11, I. 3-6 and 63-67 and col. 12,I. 1-12) when the ambulatory orthosis support is associated with the joint of the patient.

As for claim 53, Walton discloses in Figure 15 and column 10, lines 40-42 that the display can be part of a television (198).

As for claim 56, Figures 13 and 21 of Walton provides examples of the display having targets (target 136 and the track 230) to be reached by the patient through the joint movement. See column 8, lines 46-52 and column 12, lines 1-12.

As for claim 59 as broadly as recited, the support portion includes a hinge (buckle (5)) and thus the orthosis comprises a hinge.

Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. Claims 27, 31 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman in view of Kramer (6,059,506). In the alternative if the flex sensors of Zimmerman are not viewed as strain sensors, Kramer teaches in column 23, lines 16-26 that it is known to use strain flex sensors in order to measure the position of the fingers and hand in order to provide feedback to the user. Thus, Kramer teaches a motivation to select a strain flex sensor for the flex sensors (40) of the



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Zimmerman device in order to provide feedback to the controller regarding the motion of the user's hand and fingers.

As for claims 31 and 57, see the above discussion.

As for claim 58, Zimmerman discloses in column 4, lines 19-52 that the sensor can be a flex sensor. In addition as discussed above, Kramer also teaches in column 23, lines 16-26 that flex sensors and other sensors are position sensors that measure finger and hand movement and provide feedback to user. Thus, one having ordinary skill in the art would have know to select a position sensor to determine position of the finger. Kramer also shows alternative sensors arranged between fingers, such as that in Fig. 5I and column 15, lines 11-35, in which the position of the fingers includes a position sensor connected to hinge. This arranged provides for reinforcement in the glove. As such one having ordinary skill in the art would have been motivated to substitute the hinge of Zimmerman for that taught by Kramer in order to provide reinforcement to the glove of Zimmerman.

12. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman in view of Pitkanen. Zimmerman discloses in column 3, lines 31-52, column 4, lines 19-24 and column 5, lines 25-46 the use of flex sensors and position sensors (potentiometers) to determine the spatial positioning of the hand and fingers in motion in two dimensions. However, there is no discussion of one dimension corresponding to the output of a position sensor and motion of the other dimension corresponding to an output of a strain sensor. The Pitkanen device, which is used to display body motion during exercise, teaches a displayed cross-hair motion in two

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dimensions (Figs. 5A-C) correlated with the strain and position of the joint by way of position and strain sensors (column 4, lines 23-55). While Pitkanen does not disclose the particulars of the first and second dimensions corresponding to the output of which sensor, such a correspondence would reduce and simplify processing of the sensor data. Absent a teaching as to the criticality of such an arrangement, one having ordinary skill in the art would have known to display the cursor such that the cursor moves in a first dimension corresponding to the position sensor and in a second dimension corresponding to the strain gage in order to reduce and simplify the processing of the data from the sensors.

13. Claims 24-26 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark (5,823,975) in view of Walton. Stark discloses in Figures 1-2, 9, and 14, column 7, lines 36-58, column 8, lines 10-60, and column 15, lines 1-39 a method of performing coordination exercises for neuromotor training comprising flexing a joint (col. 5, I 17-22; Figs. 1 and 14) of a patient such that a sine or square waveform moves to reach a target position (that of the prescribed regiment) on the display (col. 15, I. 33) at a selected, predetermined time, the motion of the waveform being correlated with the motion or strain of the joint (Figs. 1 and 14) by way of the sensor (col. 5, I. 34-51, col. 7, I. 40-43, and col. 15, I. 32-39 discuss strain gages 114,115 and position sensor 131) in an ambulatory orthosis placed at the joint, the ambulatory orthosis comprising a support portion that fits around the joint (e.g. Figs. 1 and 14) such that the ambulatory orthosis is carried by the patient during the flexing step (see Figs. 1 and 14). However, the sine or square waveform may not be considered a cursor on a

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display. As such, Walton is being cited to teach an alternative display format for sensor information in a cursor format to reach a target position. Walton teaches various formats for presenting sensor information, including a waveform such as that in Fig. 18 (col. 11, I. 3-13), a projectile (134) to a target (136) as that in Fig. 13 (col. 8, I. 46-52) and cursor in the form of a cartoon character in Figure 21 (col. 12, I. 1-12). Thus, Walton suggests other displayable formats for displaying sensor information, including in a specific discussion of a cursor format, which provides excitement, entertainment and incentive to a physical regiment (col. 2, I. 65-col. 3, I. 1 and col. 12, I. 8-12). Thus, one having ordinary skill in the art would have been motivated to substitute a cursor, as taught by Walton, for a waveform of Stark in order to provide the user with more excitement, entertainment and incentive during a physical regiment.

As for claim 25, see Figures 1, 9 and 14 of Stark, disclosing a first support portion (e.g. 103,110) that fits around a first body portion on a first side of a joint, a second support portion (e.g. 101,112) that fits around a second body portion on the opposite side of the joint from the first body portion, a flexible connection (hinge 117) connecting the first and second support portions, and a position sensor (131;col. 7, I. 40-49) operably connected to the flexible connection such that the position sensor detects the relative orientation of the first support portions with respect to the second support portions.

As for claims 26 and 51, Stark discloses in column 8, line 61 – column 9, line 21 and Figure 9 that the sensor (strain gages 114, 115) is operably connected to a portable controller (116) comprising a digital microprocessor (164).

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As for claim 50, see the above discussion of claim 24. Stark discloses in Figures 1-2, 9, and 14, column 7, lines 36-58, column 8, lines 10-60, and column 15, lines 1-39 an ambulatory orthosis system (figs. 1 and 14 shown ambulatory) comprising a display (e.g. 176 or 336), a support portion that fits around a joint (col. 5, I. 17-22) and is carried by the patient during use (see figs. 1 and 14), a controller (116) operably connected to a sensor (e.g. strain gages 114, 115;col. 8, I. 20-39), wherein the controller controls the display based on signals from the sensors (such as torque load; col. 15, I. 32-39) and wherein the patient, flexing a joint, causes a sine or square waveform movement on the display, in which the motion of the waveform is correlated with the strain of the joint as detected by the sensor (col. 15, I. 32-39) in an ambulatory orthosis system when the ambulatory orthosis system is associated with the of the patient. See the teaching regarding the cursor with respect to Walton above and claim 24.

14. Claims 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walton. The size of the unit 2 (especially the embodiment shown in Fig. 6) of Walton is such that is sized and configured to fit around the knee or elbow. In addition, Walton suggests in column 3, lines 4-6 and column 4, lines 52-53 that the unit can be placed on other parts of the body (see "arms, and/or legs" in column 3 and "waist, wrist, *etc.*" in column 4) in order to provide exercise and physical simulation to various parts of the body (col. 2, I. 65 – col. 3, I. 6). Thus, one having ordinary skill in the art would have been motivated to place the unit such that it fits around the knee or elbow in order to provide exercise and physical simulation to various parts of the body.

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Response to Arguments

15. Applicant's arguments with respect to claims 24-31 have been considered but are most in view of the new ground(s) of rejection.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise M Pothier whose telephone number is (703) 308-0993. The examiner can normally be reached on Monday -Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Denise Pothier Primary Examiner April 6, 2003

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